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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,812	06/29/2001	Thomas D. Madden	16303-008030	6998
500	7590	01/22/2004	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/896,812

### Applicant(s)

MADDEN ET AL.

### Examiner

Gollamudi S Kishore, PhD

### Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36,38-41 and 43-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 44-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-36,38-41,43 and 64-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims included in the prosecution are 32-36, 38-41, 43 and 64-67.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 38-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirpotin (6,110,491).

Kirpotin as also pointed out in the previous action, discloses liposomal compositions wherein the active agent is in the precipitated form.

The active agent according to Kirpotin can be any compound with ionizable groups. The active agents suggested by Kirpotin are antineoplastic agents, doxorubicin, vincristin, vinblastine and others. The liposomes are made of various phospholipids including those taught by WO or sphingomyelin; the liposomes contain cholesterol. The lipid drug ratios in Kirpotin also appear to fall within the claimed ratios (abstract; col. 4, line 54 through col. 6, line 18; col. 9, lines 22-67; examples and claims). What are lacking in Kirpotin are the teachings of the anti-neoplastic drug, camptothecin. Although specific examples in Kirpotin use only doxorubicin, it would have been obvious to one of ordinary skill in the art to use vinca alkaloids as the active agents with a reasonable

expectation of success since Kirpotin specifically suggests these agents for the encapsulation in the liposomes.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments mostly pertain to the differences in the method of preparation between Kirpotin and instant application. These arguments are not found to be persuasive since the claims are drawn to compositions and not method of preparation claims.

3. Claims 32-36, 38-41, 43 and 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13816 in combination with Kirpotin (6,110,491).

As pointed out in the previous action, WO discloses liposomal formulations containing various camptothecins in a precipitated form. According to WO, any phospholipid capable of forming liposomes can be used in preparing liposomes. The liposomes also contain cholesterol. The drug-lipid ratios taught by WO appear to fall within the claimed ratios (abstract, page 8, lines 8 through page 11, line 15; page 12, lines 1-7, Examples 3 and 4 and claims). What are lacking in WO are the teachings of the use of sphingomyelin as the liposome-forming lipid.

Kirpotin as also pointed out in the previous action, discloses liposomal compositions wherein the active agent is in the precipitated form.

The active agent according to Kirpotin can be any compound with ionizable groups. The active agents taught by Kirpotin are antineoplastic agents, doxorubicin, vincristin, vinblastine and others. The liposomes are made of various phospholipids including those taught by WO or sphingomyelin; the liposomes contain cholesterol. The lipid drug

ratios in Kirpotin also appear to fall within the claimed ratios (abstract; col. 4, line 54 through col. 6, line 18; col. 9, lines 22-67; examples and claims). What are lacking in Kirpotin are the teachings of the anti-neoplastic drug, camptothecin.

The use of sphingomyelin as the bilayer forming lipid in the liposomes of WO would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Kirpotin while disclosing similar liposomes, teaches that sphingomyelin besides the phospholipids could be used in the formation of liposomes. Alternately, the use of camptothecins taught by WO as the anti-neoplastic drug in the liposomes of Kirpotin would have been obvious to one of ordinary skill in the art since Kirpotin teaches that any ionizable drug can be used in the liposomes.

Applicant's arguments have been considered, but are deemed to be moot in view of these new rejections made based on applicant's amendments to the claims.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is 703 308 2440. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703 308 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.

  
Gollamudi S Kishore, PhD  
Primary Examiner  
Art Unit 1615

GSK